4

DATA EVALUATION RECORD

BREWER'S YEAST EXTRACT (*Saccharomyces cerevisiae*) (YEAST HYDROLYSATE OR)

STUDY TYPES: **Product Identity and Composition (OPPTS 880.1100)**
Description of Starting Materials, Production and Formulation Process (OPPTS 880.1200)
Discussion of Formation of Impurities (OPPTS 880.1400)
Preliminary Analysis (OPPTS 830.1700)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)
Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)

MRIDs 46395001 and 46419601

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1801 Bell Street
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 05-001

Primary Reviewer:
Susan Chang, M.S.

Signature: _____
Date: FEB 09 2005

Secondary Reviewers:
Sylvia Milanez, Ph.D., D.A.B.T.

Signature: _____
Date: FEB 09 2005

Robert H. Ross, M.S., Group Leader

Signature: _____
Date: FEB 09 2005

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: _____
Date: FEB 09 2005

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

DATA EVALUATION RECORD

EPA Secondary Reviewer:

STUDY TYPE:	Product Identity and Composition (OPPTS 880.1100) Description of Starting Materials, Production and Formulation Process (OPPTS 880.1200) Discussion of Formation of Impurities (OPPTS 880.1400) Preliminary Analysis (OPPTS 830.1700) Certified Limits (OPPTS 830.1750) Enforcement Analytical Method (OPPTS 830.1800) Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)
MRID NOS:	46395001 and 46419601
DP BARCODE NO:	DP311565
CASE NO:	Not reported
DECISION NO:	351488
TEST MATERIAL:	Yeast Hydrolysate OR (EPA Reg No. 73512-G; 2.5% Brewers yeast extract from *Saccharomyces cerevisiae*, a.i.)
PROJECT NO:	MOR 3B
SPONSOR:	Morse Enterprises Limited, Inc., Miami, FL
TESTING FACILITY:	Morse Enterprises Limited, Inc., Miami, FL
TITLE OF REPORT:	Yeast Hydrolysate OR - Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients (MRID 46395001) and Yeast Hydrolysate OR - Analysis of Samples, Certification of Ingredient Limits and Analytical Methods for Certified Limits and Physical and Chemical Properties (MRID 46419601)
AUTHOR:	Irwin S. Morse
STUDY COMPLETED:	October 26, 2004
GOOD LABORATORY PRACTICE:	Not GLP Compliant; based on accepted scientific and/or commercial practice

*Inert ing

Inert ingredient information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

CONCLUSION: Yeast Hydrolysate OR is a liquid manufacturing use product. This product is only for formulation into end use "KeyPlex" products for use on all food commodities, turf, and ornamentals. The difference between this product and the original registered product (Yeast Hydrolysate Liquid Manufacturing Use Product, EPA Reg. No. 73512-2) is that [redacted] were removed from the original product and the concentration of [redacted] is increased. The active ingredient is 2.50% w/w brewers yeast extract from *Saccharomyces cerevisiae* [redacted] The inerts are [redacted] The ingredients are either GRAS, exempt from a tolerance, or on EPA inert list 4. The CAS Nos. for [redacted] were incorrect on the CSF. The label is in agreement with the CSF concerning the amount of the active ingredient, but the name of the product differs slightly. The description of the starting materials and the production process were adequately addressed. No unintentional impurities are formed during manufacture (although a typographic error in the text made this unclear). Preliminary analysis and an enforcement analytical method were not addressed. The certified limits of most ingredients are within the recommended range in guideline OPPTS 830.1750, the exceptions being the active ingredient (±12% v.s. ±5% per guideline) and [redacted] per guideline). The physical/chemical properties oxidation/reduction, explodability, miscibility, and viscosity were not addressed.

CLASSIFICATION: **UNACCEPTABLE**, but upgradable if the registrant 1) corrects the CAS Nos. for [redacted] on the CSF and lists the active ingredient first on the CSF; 2) consistently lists the name of the product on the label and the CSF; 3) explains the amount of [redacted] used during manufacture; 4) confirms that there are no unintentional impurities formed during manufacture; and 5) addresses oxidation/reduction, explodability, miscibility, and viscosity of the product.

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

*Inert in

Inert ingredient information may be entitled to confidential treatment

Test Material: Yeast Hydrolysate OR containing 2.50% w/w brewers yeast extract from *Saccharomyces cerevisiae* as a.i.

I. PRODUCT IDENTITY AND COMPOSITION: Yeast Hydrolysate OR (EPA Reg. No. 73512-G) is a liquid manufacturing use product. This product is only for formulation into end use "KeyPlex" products for use on all food commodities, turf, and ornamentals. The difference between this product and the original registered product (Yeast Hydrolysate Liquid Manufacturing Use Product, EPA Reg. No. 73512-2) is that [redacted] were removed from the original product and the concentration of [redacted] is increased. The active ingredient is 2.50% w/w brewers yeast extract from *Saccharomyces cerevisiae*. The registrant needs to list the active ingredient first on the CSF. The inerts are [redacted] The ingredients are either GRAS, exempt from a tolerance, or on EPA inert list 4 (See Table 1 below). The label is in agreement with the CSF concerning the amount of the active ingredient, but the name of the product differs slightly, i.e., the CSF states "Yeast Hydrolysate OR" and the label states "Yeast Hydrolysate OR Liquid."

Deficiencies: The registrant needs to correct the CAS Nos. for [redacted] on the CSF (See Table 1 below), and resolve the discrepancies between the name of the product on the label and the CSF.

TABLE 1. Nominal CSF concentrations and limits for Yeast Hydrolysate OR[a]							
Ingredients	CAS No.	GRAS/Exemption	PC Code	Purpose	Concentration (% by weight)		
					Nominal	Lower	Upper
Active Ingredient							
Brewers Yeast Extract from *Saccharomyces cerevisiae*, [redacted]	8013-01-2	GRAS 184.1983	100053	Active	2.5%	2.2%	2.8%
Inert ingredients							
[redacted]							

[a] Data from CSF in MRID 46419601.

[b] [redacted] is listed on the CSF for [redacted] Chemfinder.com indicates that [redacted]

[c] [redacted] but [redacted] which is also used for [redacted] is not on the EPA inert list and has no assigned PC code.

Inert ingredient information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

II. DESCRIPTION OF OF STARTING MATERIALS, PRODUCTION AND FORMULATION PROCESS: The beginning materials are [redacted] Brewers yeast extract from *Saccharomyces cerevisiae* [redacted]

[redacted]

III. DISCUSSION OF FORMATION OF IMPURITIES: The starting material is brewer's yeast which is a safe and natural product and chemicals that generally do not produce hazardous materials. The study (MRID 46395001) indicated that the yeast hydrolysate product has been used for a number of years without any observed or reported deleterious effects. The study (p. 65 of MRID 46395001) stated that "no intentional products are formed as it is currently manufactured." The reviewer assumes that this is a typographic error, and, based on the next sentence in the text "this discussion of the formation of unintentional ingredients applied to both the yeast hydrolysate Manufacturing Use Product," that they meant to say no unintentional ingredients are formed as it is currently manufactured.

Deficiencies: The above described sentence in MRID 46395001 should be corrected or explained.

IV. PRELIMINARY ANALYSIS: Preliminary analysis of five batches of the product was not conducted.

Deficiencies: Preliminary analysis was not necessary because the active ingredient is registered as the MP Yeast Hydrolysate Liquid (EPA Reg. No. 73512-2).

V. CERTIFIED LIMITS: Yeast Hydrolysate OR contains 2.5% Brewers yeast extract (limits of 2.2-2.8% w/w). The upper and lower certified limits (±12%) are out of the recommended

range (±5%) in guideline OPPTS 830.1750. The lower and upper certified limits of the inerts are [redacted] The upper and lower certified limits [redacted] of [redacted] are out of the recommended range (±5%) in guideline. The certified limits of [redacted] are within the recommended range in guideline, but the limits of the other inert ingredients are slightly out of the range recommended in the guideline which maybe due to rounding off the decimal places.

Deficiencies: The upper and lower certified limits of the active ingredient and the inert [redacted] are out of the recommended range in Guideline OPPTS 830.1750. No explanation was given.

VI. **ENFORCEMENT ANALYTICAL METHOD:** No specific enforcement analytical method was mentioned in the studies and is not needed because the active ingredient is registered as the MP Yeast Hydrolysate Liquid (EPA Reg. No. 73512-2). Quality control tests were described in detail. In MRID 46419601: [redacted]

Deficiencies: None

VII. **PHYSICAL AND CHEMICAL CHARACTERISTICS:**

1. **Methods:** Not reported.

2. **Results:** The physical/chemical properties are listed in Table 2.

3. **Deficiencies:** Oxidation/reduction, explodability, miscibility, and viscosity were not addressed.

TABLE 2. Physical and Chemical Properties for Yeast Hydrolysate OR[a]		
Guideline Reference No./Property	Description of Result	Methods
830.6302 Color	Light brown	Not reported
830.6303 Physical State	Opaque liquid	Not reported
830.6304 Odor	Slightly sweet	Not reported
830.6313 Stability	Not required for MP	
830.6314 Oxidation/Reduction: Chemical Incompatibility	Not addressed	
830.6315 Flammability	Not flammable	Not reported
830.6316 Explodability	Not addressed	
830.6317 Storage Stability	The product is used soon after production and no later than five weeks after production.	Not reported
830.6319 Miscibility	Not addressed	
830.6320 Corrosion Characteristics	Product is not corrosive based on no reporting of corrosiveness in the manufacturing plant or in the field, the pH of 5.8-6.0, storing in polypropylene bulk containers, and sold in plastic containers.	Not reported
830.6321 Dielectric Breakdown Voltage	Not required for MP	
830.7000 pH	5.8-6.0 (CSF)	Not reported
830.7050 UV/Visible	Not required for MP	
830.7100 Viscosity	Not addressed	
830.7200 Melting Range	Not required for MP	
830.7220 Boiling Range	Approximately 100°C (boiling point of water); the product contains 86.37% water, and peptides, proteins, and amino acids which are solids.	Not reported
830.7300 Specific Gravity; Bulk Density	1.05-1.06; 8.89 lb/gal	Not reported
830.7370 Dissociation Constant in Water	Not required for MP	
830.7520 Particle Size/Distribution	Not required for MP	
830.7550 Partition Coefficient	Not required for MP	
830.7840 Water Solubility	Not required for MP	
830.7950 Vapor Pressure	Product is not volatile.	Not reported

[a] Data from MRID 46419601.

VIII. ADDITIONAL REVIEWER'S COMMENTS: None